

Fig. 1

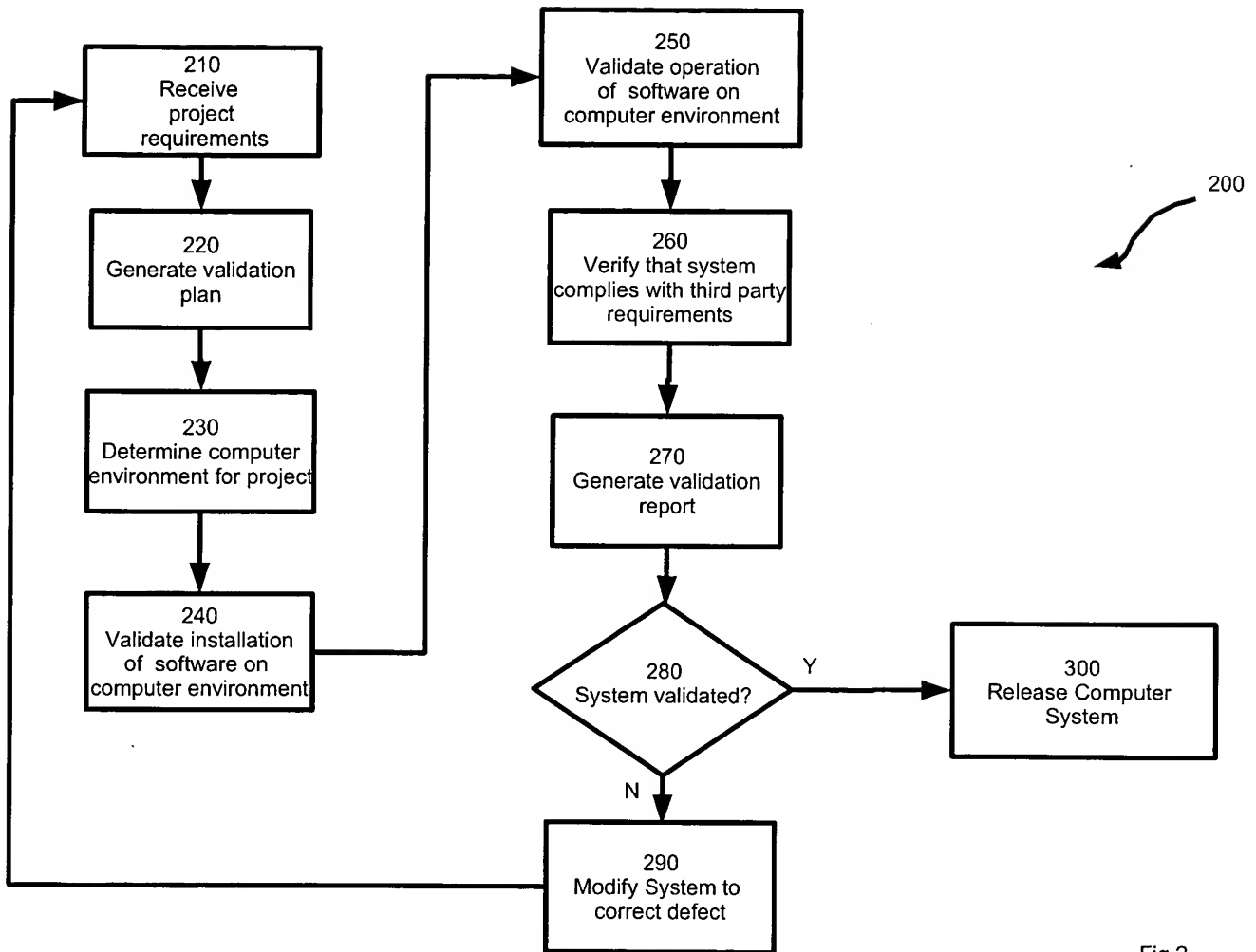


Fig.2

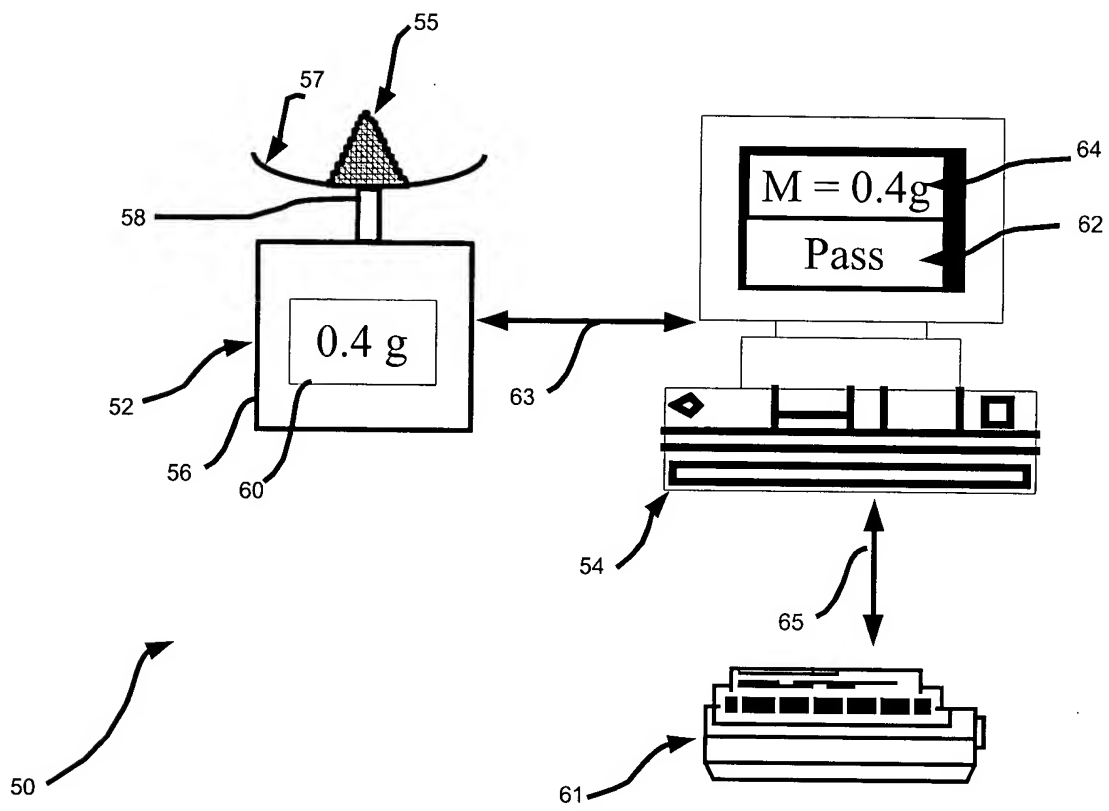


Fig.3

V

210i      210j      210k

**PROJECT INFORMATION**

210b → Project ID:

210c → Project Name:

210d → Project Start Date:       Completion Date:

210e → Created By:

210f → Vendor:

210g → Name:       210g → Version:

Company:

Division:

Department:

Location:

Add
 Save
Exit

Software Components
Interface Component

Component	Detail
Production Manager	This is used by system administrators to c
Digital Signature repository	Keeps track of users signatures
Browser	This is a viewing tool to browse the data
Archive	Logging tool for measurements

Component:

Detail:

This configured by a system administrator to keep track of which users run the Weightmate, and to the level at which the user is allowed to access Weightmate during a production run of measuring masses of pharmaceutical ingredients.

Add
Save
Delete

R

210l      210m      210n      210k

**PROJECT INFORM...**

Start
My Computer
Validator - Microsoft Visua...
Document1 - Microsoft W...

11:11 AM

Fig.4

# V A L I D A T O R

**USER REQUIREMENT**

Project Name:

Requirement	QType
▶ Must not overwrite USB printer driver	INSTALLATION QUALIFICATION
Must work with Y/M/D date format	INSTALLATION QUALIFICATION
Must be able to run while minimized	OPERATIONAL QUALIFICATION
Must be 21 CFR Part 11 compliant	THIRD PARTY QUALIFICATION

Qualification Type:

Requirement:

210<sub>2</sub>

210c

210o

210p

210q

210r

210o

Fig.5

Validation Plan

Project Name: Weightmate

220c

210c

220

220j Approvals

220g Periodic Review

220d Validation Scope

220l References

220h Acceptance Criteria

220e Software Constraints

220k - Test -

220f Hardware Description

System

Components in SCOPE

☐ Archive  
☒ Production Manager  
☒ Browser  
☒ Digital Signature repository

Reason for not in SCOPE

Archive not implemented at this time due to Excel Interface being used for same purpose

Interfaces

Interfaces in SCOPE

☒ Excel  
☐ Oracle

Reason for not in SCOPE

Oracle interface not implemented at this time due to Excel Interface being used for same purpose

Save

Print Validation Plan

Exit

210i

210n

210k

210l

210m

210j

Fig. 6

**DETAILED TEST PLAN** 220<sub>2</sub>

220k 220l 220o

Project Name:  220m 220n

210c

**TEST CASES**

Req No	Case No	Test objective	Acceptance Criteria
1	1	The install of the USB driver for the scale	USB driver still located in OS directory
1	2	USB printer still working after install?	Print test page to USB printer
2	1	Verify OS set to Y/M/D format	View OS date/time format setting
2	2	Create sample Y/M/D records	Sample dates accurately saved
3	1	Examine behaviour while minimized	Calculations proceed during minimize?
4		121CFR Part 11 compliance – verification	Create sample record and save with dig

210o 210o 210p 210q 210r

Test Case No:  220m

Requirement No:  210o

Test objective: The installation of the USB driver for the scales must not overwrite the existing USB printer driver on the workstation

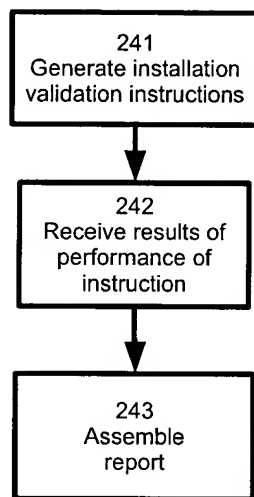
Acceptance Criteria: USB Printer driver still located in OS driver directory 220n

Comments:

Must not overwrite USB printer driver 210o

Exit Add Save

Fig. 7



Step  
240

Fig.8



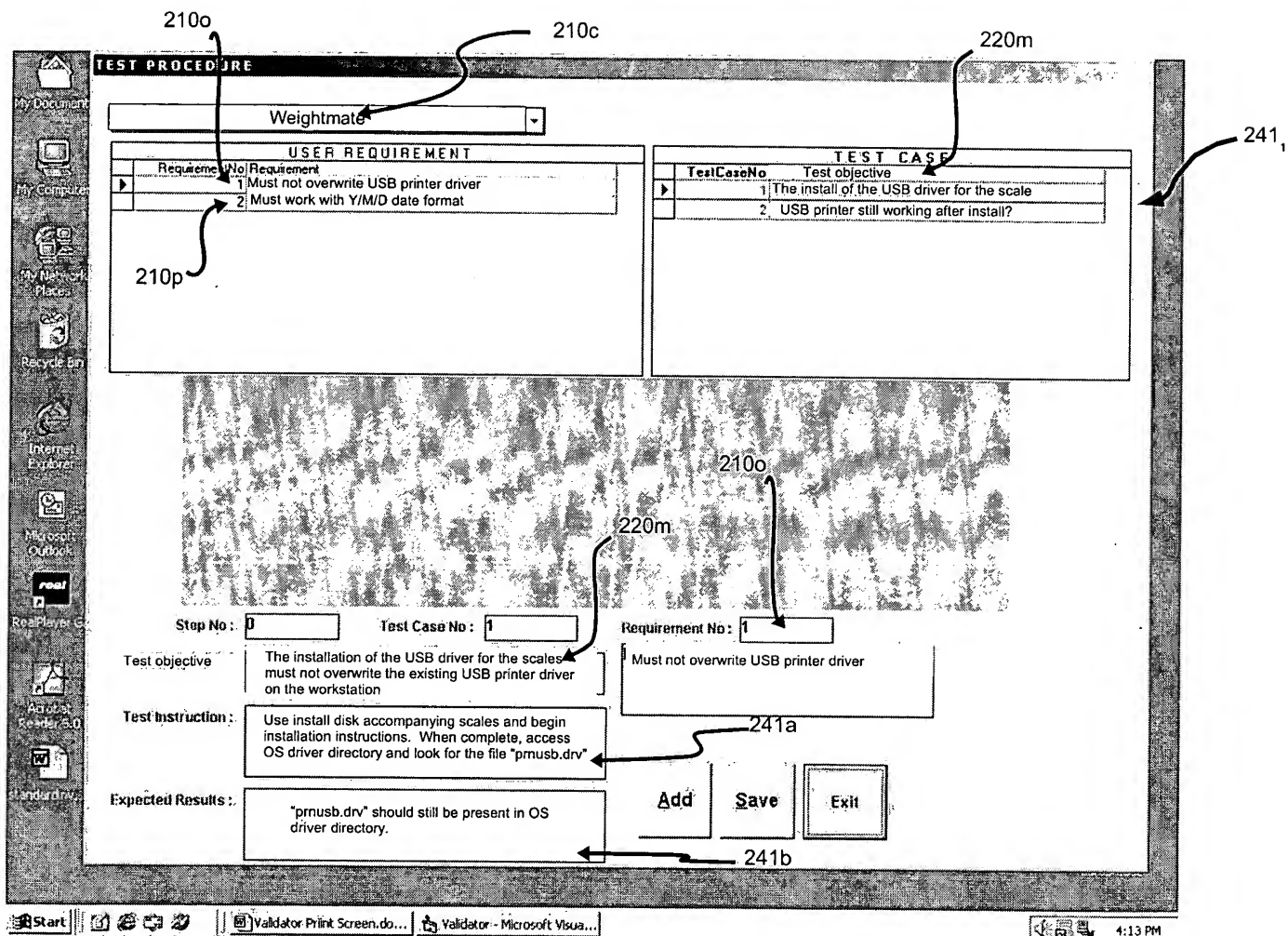


Fig. 9

Incident Report Form

Project Name:

IncidentID	IncidentDesc	CorrectiveAction	Pass/Fail
1	USB Printer driver not found as expected	Investigate whether printer	Fail

Incident ID:  Test Case No:  Requirement No:

Objective: The installation of the USB driver for the scales must not overwrite the existing USB printer driver on the workstation

Incident: USB Printer driver not found as expected

Corrective Action: Investigate whether printer driver can be reinstalled.

Pass/Fail:

Add Save Print Incident Report Form Exit

Fig. 10

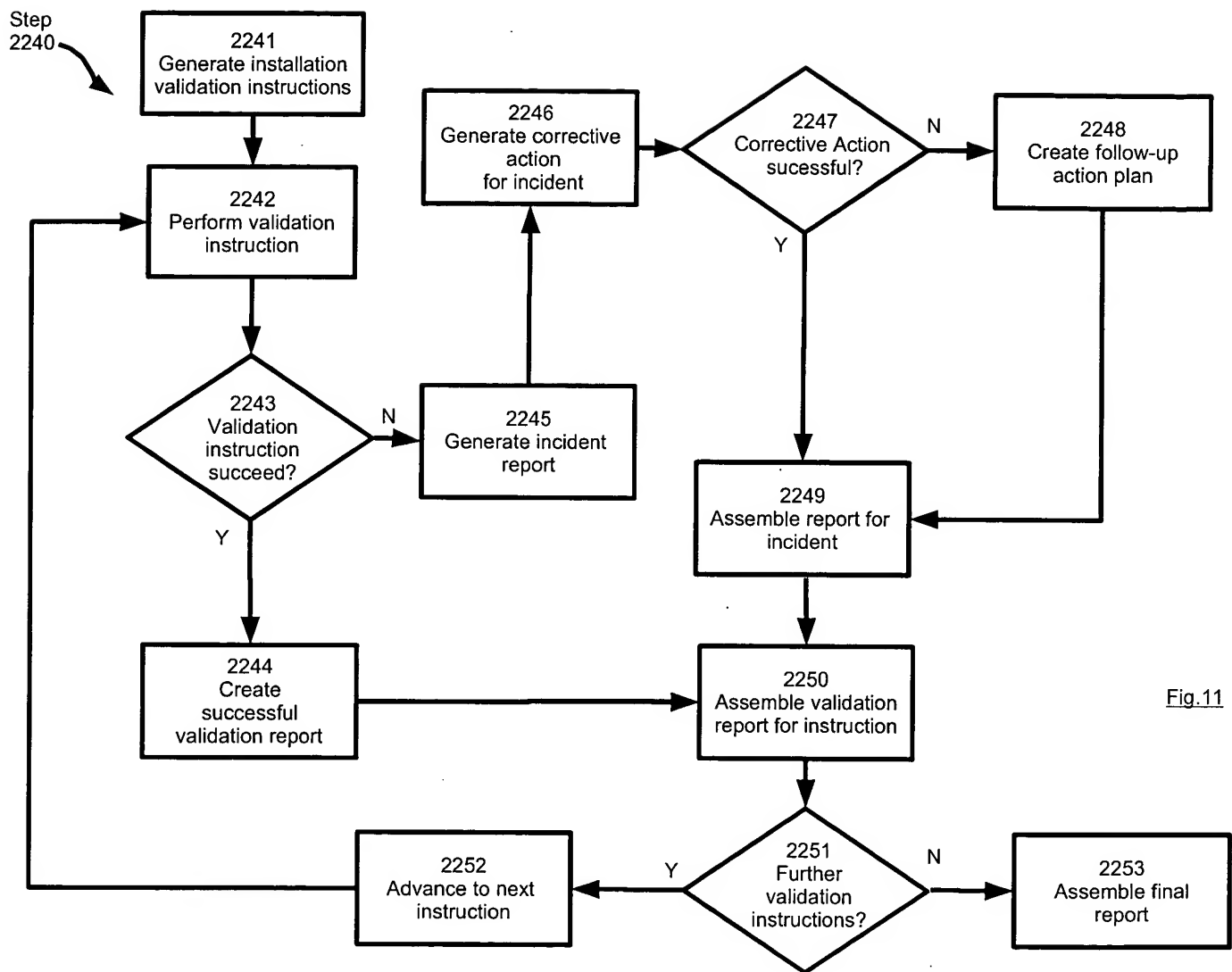
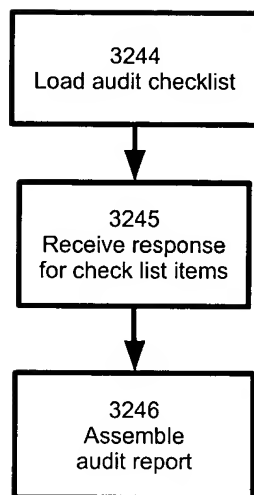
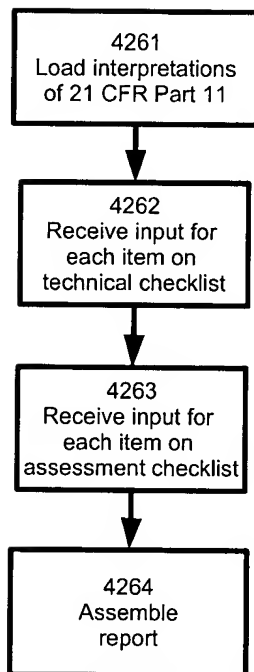


Fig.11



3240

Fig.12



4260

Fig.13

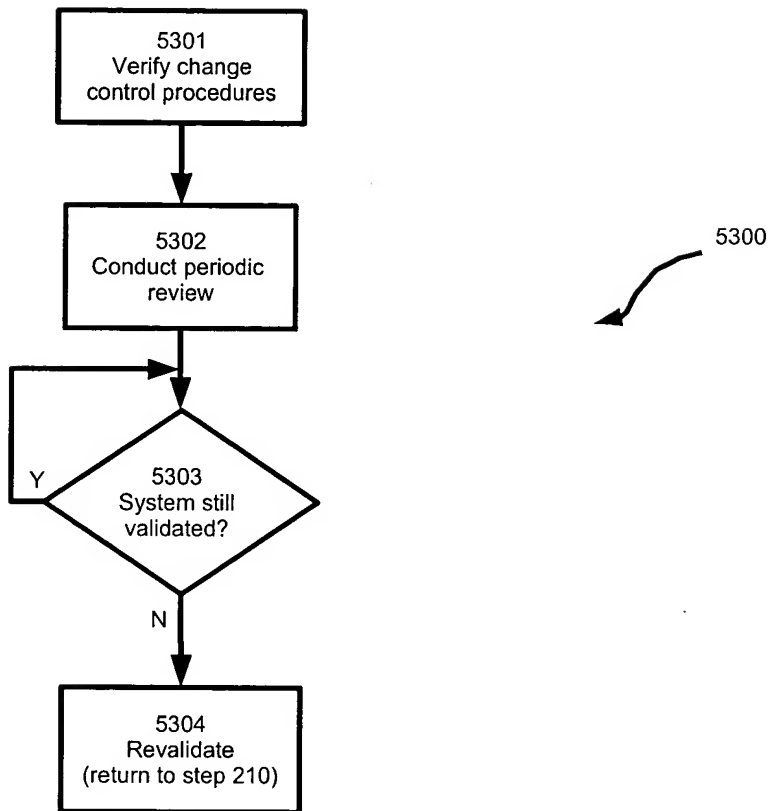


Fig.14

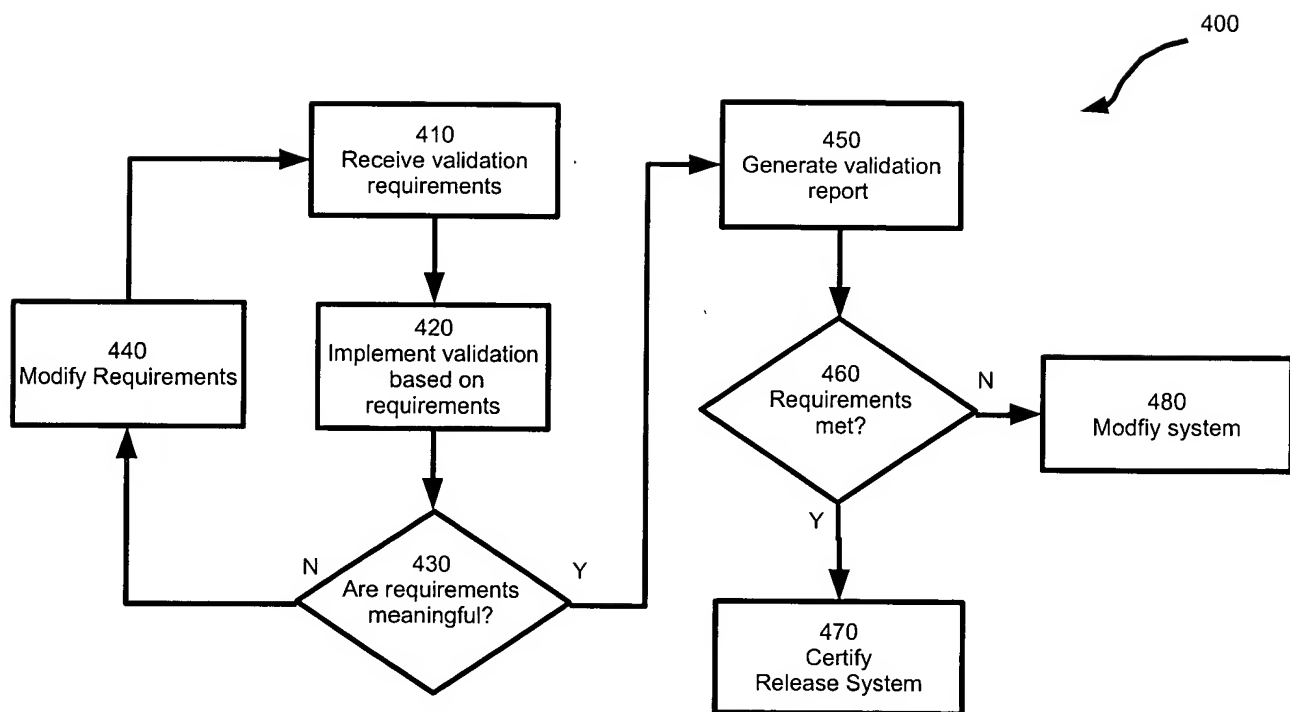


Fig.15